

\* \* \* \* \*

(k) \* \* \*

(13) In the case of cardiovascular disease screening tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease, subject to the conditions specified in §410.17 of this chapter.

(14) In the case of diabetes screening tests furnished to an individual at risk for diabetes for the purpose of the early detection of that disease, subject to the conditions specified in §410.18 of this chapter.

\* \* \* \* \*

**Subpart J--Financial Relationships Between Physicians and Entities Furnishing Designated Health Services**

17. Section 411.351 is amended by revising the definition of "entity" to read as follows:

**§411.351 Definitions.**

\* \* \* \* \*

Entity means--

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated

\*  
*Under arrangement  
Issue*

association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it--

(i) Is the person or entity that has performed the DHS, or

(ii) Presented a claim or caused a claim to be presented for Medicare benefits for the DHS.

(2) For purposes of this subpart, "entity" includes a health plan, managed care organization (MCO), provider sponsored organization (PSO), or independent practice association (IPA) that employs a supplier or operates a facility that could accept reassignment from a supplier pursuant to §424.80 of this chapter, with respect to any designated health services provided by that supplier; "entity" does not include a health care delivery system that is a health plan (as defined in §1001.952(1) of this title), or any MCO, PSO or IPA with which a health plan contracts for services provided to plan enrollees.

(3) For purposes of this subpart, "entity" does not include a physician's practice when it bills Medicare for a diagnostic testing accordance with §414.50 of this chapter (Physician billing for purchased diagnostic tests) and

section 30.2.9 of the Internet-Only Manual, Pub.100-04,  
Chapter 1, General Billing Requirements.

\* \* \* \* \*

18. Section 411.353 is amended by adding paragraph  
(g) to read as follows:

**§411.353 Prohibition on certain referrals by physicians and  
limitations on billing.**

\* \* \* \* \*

(g) Denial of payment for services furnished under a  
prohibited referral. When payment for a designated health  
service is denied on the basis that the service was  
furnished pursuant to a prohibited referral, and such  
payment denial is appealed, the burden is on the entity  
submitting the claim for payment to establish that the  
service was not furnished pursuant to a prohibited referral  
(and not on CMS or its contractors to establish that the  
service was furnished pursuant to a prohibited referral).

19. Section 411.354 is amended by revising paragraphs  
(b)(3)(i) and (d)(1) to read as follows:

**§411.354 Financial relationship, compensation, and  
ownership or investment interest**

\* \* \* \* \*

(b) \* \* \*

(3) \* \* \*